

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-11, 14-17 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not seen where the amorphous form I is different from the crystalline form 1 of the instant claim 1. The method of making the amorphous form I is by grinding the special crystalline form. When a crystalline form is ground, microcrystals are formed. If the crystals are extremely small, then X-ray powder diffraction cannot be done since the crystalline diffractions are so slight, the graph appears to be flat. However, the substance remains in crystalline form. There are no directly comparative tests showing that the amorphous form I is different from the crystalline form of claim 1. The method of making the amorphous form I is no different from making of the crystalline form of claim 1 except for the milling process. So it is not seen where applicant has possession of two different amorphous forms of montelukast free acid. Further, what is the difference between amorphous form I and form II? The peaks disclosed in claim 8 appear to fall within the peaks of figure 9 (of form II). Further the October 2002 ACPS meeting teaches that amorphous solids consist of disordered arrangements of

Art Unit: 1625

molecules. How can disordered arrangements of molecules result in two different amorphous forms as instantly claimed?

***Claim Rejections - 35 USC § 102/103***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 480717.

102 reasons: EP teaches montelukast free acid and its use to treat asthma. This anticipates the instant claims.

103 reasons: EP teaches montelukast free acid and its use to treat asthma. The difference between the teachings of the EP and the instant claims is that the EP does not specifically state the physical form or any tests (X-ray powder diffraction or DSC thermogram) to show what form

Art Unit: 1625

the montelukast free acid has been made by the EP. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make montelukast free acid as taught by the EP with the reasonable expectation of getting some solid form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

/D. Margaret Seaman/  
Primary Examiner, Art Unit 1625